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14. ABSTRACT

Breast cancer survivors are at elevated risk for developing a new breast cancer compared to healthy women, and are at considerable risk for breast cancer recurrence. According to the American Society of Clinical Oncology, survivors should undergo careful breast cancer surveillance including annual mammography and breast self-exam. However, studies indicate that breast cancer surveillance among African American survivors, particularly mammography, is low, especially given the higher risk of survivors as a group. The promotion of breast cancer surveillance among African American survivors is an area that deserves special attention as cancers detected early are more treatable. One promising strategy is the adaptation of a peer-led intervention developed to increase screening among healthy African American women. The objectives of the current study are: 1) to evaluate the impact of a peer-led intervention on breast cancer surveillance intention and adherence among African American breast cancer survivors through a randomized controlled trial; and 2) to investigate the mediational pathways through which the peer-led intervention impacts surveillance intention and adherence.

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INTRODUCTION: Breast cancer survivors are at elevated risk for developing a new breast cancer compared to healthy women, and are at considerable risk for breast cancer recurrence. According to the American Society of Clinical Oncology, survivors should undergo careful breast cancer surveillance including annual mammography and breast self-exam. However, studies indicate that breast cancer surveillance among African American survivors, particularly mammography, is low, especially given the higher risk of survivors as a group. The promotion of breast cancer surveillance among African American survivors is an area that deserves special attention as cancers detected early are more treatable. One promising strategy is the adaptation of a peer-led intervention developed to increase screening among healthy African American women. The objectives of the current study are: 1) to evaluate the impact of a peer-led intervention on breast cancer surveillance intention and adherence among African American breast cancer survivors through a randomized controlled trial; and 2) to investigate the mediational pathways through which the peer-led intervention impacts surveillance intention and adherence. 409 participants will be recruited and randomized over the course of the study. Participants will be African American women age 20-74 years and diagnosed with Stage I, II or III breast cancer who previously participated in an ongoing parent project and are at least 3 months post-treatment. Once informed consent is obtained, participants will be contacted via telephone to complete a baseline interview assessing sociodemographic information, breast cancer surveillance intention and adherence, and attitudinal/cognitive variables. Participants will then be assigned to either the survivor surveillance intervention condition or control condition and those in the intervention condition will participate in the intervention. One month following the intervention, participants in both conditions will complete a telephone interview to assess breast cancer screening adherence and changes in attitudinal/cognitive variables from baseline to post-intervention. Fourteen months after the intervention, women in both conditions will be contacted again in order to assess surveillance intention and adherence.

BODY: The approved statement of work for the current study is included as Appendix A. **Please note**: DoD Human Subject Protection Review was completed and approval received in November 2004. The notice of MSSM IRB renewal approval is in Appendix B. We are awaiting approval on amendments to the protocol for which MSSM IRB approval was obtained (see Appendix B) and submitted to the DoD in April 2006. These modifications will greatly facilitate recruitment and study implementation as they describe the expansion of recruitment efforts beyond the DoD study titled "Behavior, Estrogen Metabolism, and Breast Cancer Risk: A Molecular Epidemiologic Study," (HSRRB Log Number A-10862.5). These amendments are included in Appendix D. The documentation in Appendix D is also the current version approved by MSSM's IRB.

Tasks completed in the past year are described below.

A. **Task 2: Recruit participants, conduct baseline assessment interview for randomized controlled trial evaluating peer-implemented survivor surveillance intervention, and conduct intervention (months 6-30)**

   Since June 2005, no women have been recruited under the currently approved protocol.

B. **Task 3: One-month follow-up assessment interviews (Months 8-30)**

   Interviews have not been conducted under the currently approved protocol.

C. **Task 4: Fourteen-month follow up assessment interviews (Months 21-45)**

   Interviews have not been conducted under the currently approved protocol.

D. **Task 5: Interim data analyses, report and presentations**

   Interim data analyses have not been completed as no data has been collected.

D. **Continued collaboration with co-investigators and consultants to review assessment strategies and tailoring of the survivor surveillance (peer-led) intervention:** We established regular meetings that include the PI, the project coordinator, and co-investigators (Drs. Bovbjerg and Valdimarsdottir and Ms. Jandorf). These meetings focus on recruitment and implementation issues, as well as assessment strategies.

E. **Presentation at 2006 Era of Hope Conference:** Appendix C includes an abstract describing intervention development that was presented at the 2005 Era of Hope conference in Philadelphia, PA.

KEY RESEARCH ACCOMPLISHMENTS: The key accomplishment was the presentation of an abstract describing intervention development (see Appendix C).

REPORTABLE OUTCOMES: See abstract in Appendix C.

CONCLUSIONS: DoD Human Subject Protection Review was completed and approval received in November 2004. We are awaiting approval on amendments to the protocol submitted in April 2006 and for which Mount Sinai IRB approval was obtained and submitted to the DoD in April 2006. These modifications will greatly facilitate recruitment and study implementation. These amendments are included in Appendix D.

Appendix A. Approved Statement of Work

Task 1: Study start-up (Months 1-5)

a. Hire and train research assistant and data entry clerk
b. Collaborate with co-investigators and consultants to review assessment strategies and tailoring of the survivor surveillance intervention
c. Train peer interventionists (recruited from the ongoing Witness Project of Harlem)
d. Pilot test and refine unstandardized measures
e. Prepare data entry and participant tracking systems

Task 2: Recruit participants, conduct baseline assessment interview for randomized controlled trial evaluating peer-implemented survivor surveillance intervention, and conduct intervention (Months 6-30)

a. Review database of parent project to identify eligible breast cancer patients
b. Recruit 409 patients for randomized controlled trial via telephone and mail informed consent forms
c. Administer baseline assessment interview for randomized controlled trial via telephone upon receipt of signed informed consent forms (expected total of baseline interviews=409)
d. Randomize participants
e. Mail incentives ($20 money orders) for participation
f. Develop schedule of survivor surveillance intervention presentations (expected total of presentations=14)
g. Begin data entry and management

Task 3: One-month follow-up assessment interviews (Months 8-30)

a. Contact participants via telephone to administer one-month follow-up assessment interviews (expected total of one-month follow-up interviews=389 with 5% attrition from baseline)
b. Mail incentives ($20 money orders) for participation
c. Continue data entry and management

Task 4: Fourteen-month follow-up assessment interviews (Months 21-45)

a. Contact participants via telephone to administer 14-month follow-up assessment (expected total of 14-month follow-up interviews=311 with 20% attrition from 1-month follow-up)
b. Mail incentives ($20 money orders) for participation
c. Continue data entry and management

Task 5: Interim data analyses, report and presentations (Months 22-27)

a. Work with co-investigators and consultants to conduct preliminary analyses for report
b. Present preliminary results at scientific meetings

Task 6: Final data analyses, report and presentations (Months 45-48)

a. Work with co-investigators and consultants to conduct analyses for report
b. Present results at scientific meetings
c. Prepare manuscripts for publication

Appendix B. Notice of renewal approval from MSSM's IRB

Mount Sinai

Institutional Review Board
Mount Sinai School of Medicine
One Gustave L. Levy Place, Box 1075
Icahn Medical Institute Building 4-78
New York, NY 10029-6754,
Phone (212) 659-8980
Fax (212) 876-6789

Date: May 25, 2006
MSSM Project# **02-0561 0001 04 CA ***
Principal Investigator: **Hayley Thompson, Ph.D.**
Sponsor: **ARMY**

The project entitled **INCREASING BREAST CANCER SURVEILLANCE AMONG AFRICAN AMERICAN BREAST CANCER SURVIVORS** includes activities involving human subjects. The application for continuation of the research was reviewed and approved via the expedited review procedures of the Institutional Review Board of the Mount Sinai School of Medicine, in accordance with our assurance to the Department of Health and Human Services Federal Wide Assurance #00005656. The IRB determined that this research was eligible for continuation review under **expedited category 8b** as no subjects have been enrolled at this site, and no new risks have been identified.

This research has been re-approved to be conducted during the period **6/9/2006 through 6/8/2007.** In order to continue work on this research after **6/8/2007**, a continuation application must be received, reviewed and approved prior to the date of IRB approval expiration. The IRB recommends submitting a continuation application ***7 weeks prior to the expiration date*** in order to avoid a gap in IRB approval periods. Changes to the research (other than to remove immediate hazards to the human subjects) cannot be conducted without prior IRB review and approval.

IRB approval does not constitute or imply institutional support for the conduct of this research.

Sincerely yours,

Jeffrey H. Silverstein, MD

Jeffrey H. Silverstein, M.D.
Chair
Institutional Review Board
Associate Dean, Research

Appendix C. Abstract presented at 2005 Era of Hope Conference

DEVELOPMENT OF AN INTERVENTION TO INCREASE BREAST CANCER SURVEILLANCE AMONG AFRICAN AMERICAN BREAST CANCER SURVIVORS

Women diagnosed with breast cancer are at considerable risk for breast cancer recurrence and at elevated risk for developing a second primary breast cancer compared to women in the general population. Thus, breast cancer survivors represent a high-risk population for whom careful breast cancer surveillance and follow-up care is a priority. There are disparities in surveillance such that African-American (AA) survivors were approximately half as likely to have a mammogram compared to White survivors. It has also been reported that duration of medical follow-up care for AA survivors was significantly shorter than that of White survivors. These findings suggest that the promotion of recommended breast cancer surveillance among AA survivors is an area warranting special attention.

The objectives of the current Idea Award are: 1) to evaluate the impact of a peer-led survivor surveillance intervention on breast cancer surveillance intention and adherence (mammography, BSE, pelvic exam, physical examination, patient symptom history) among African American breast cancer survivors through a randomized controlled trial; and 2) to investigate the mediational pathways through which the intervention impacts surveillance intention and adherence.

In order to reach these objectives, we have developed "Survivors in Sprit," a faith-based and peer-led educational program. Presentations include: 1) an inspirational introduction, 2) testimony by at least one breast cancer survivor about her cancer detection, survival and the importance of regular surveillance; 3) review of breast cancer recurrence facts by a lay health educator; 4) discussion of concerns and myths about breast cancer recurrence and screening/surveillance that are salient among AAW; 5) review of guidelines for surveillance as established by the American Society of Clinical Oncologists; and 6) "hands-on" breast self-exam instruction using the "grid" method, which emphasizes examination of not only the breast but adjacent areas (e.g., chest, armpit).

In developing "Survivors in Spirit," we conducted a preliminary qualitative study that included key informant interviews of 10 AA breast cancer survivors. Survivors reported a number of factors that motivated or deterred them in obtaining follow-up care: a desire to maintain good health, worry and fear about recurrence, support from health care providers, familial relationships, lack of support from family and friends, relationships with other survivors, religious or spiritual faith, lack of information about post-treatment follow-up care, medical care costs and limited access to quality healthcare. These data were used to further develop the "Survivors in Spirit" intervention. To date, we have conducted two 5-hour training sessions during which we trained 8 breast cancer survivors (referred to as survivors speakers) and 15 lay health educators. All volunteers completed training pre-tests and post-tests of breast cancer recurrence knowledge. Overall, knowledge scores increased following training sessions (pre-test mean=58% correct; post-test mean=80% correct). "Survivors in Spirit" represents a promising strategy to increase breast cancer surveillance among AA survivors.

The U.S. Army Medical Research and Materiel Command under DAMD17-03-1-0454 supported this work.

Appendix D. Amendments awaiting DoD IRB approval

A. BACKGROUND: Women who have already been diagnosed with breast cancer are at substantially elevated risk for developing a second primary breast cancer [1]. The relative risk of developing a contralateral tumor among breast cancer survivors is between 1.5 to 5.5-fold higher than the risk of primary breast cancer in women in the general population [2-4]. Several authors have noted that survivors who have had breast-conserving surgery are at considerable risk of ipsilateral breast cancer recurrence [5-7]. There is general consensus that recurrences detected early are more treatable and the likelihood of achieving disease control, complete remission, or extended survival is higher [5;8].Thus, breast cancer survivors represent a high-risk population for whom careful breast cancer surveillance is a priority. According to the American Society of Clinical Oncology (ASCO), following primary treatment, breast cancer survivors should: 1) participate in annual mammography (with first post-treatment mammogram approximately 6 months after completion of radiation therapy); 2) conduct monthly breast self-exam (BSE); 3) undergo a regular pelvic exam; 4) undergo a physical examination every 3-6 months for the first 3 years then every 6-12 months for the next 2 years, then annually; and 5) provide a patient/symptom history every 3-6 months for the first three years after primary treatment, then every 6-12 months for the next 2 years, then annually [9]. However, data suggest that breast cancer survivors under-utilize surveillance modalities, particularly mammography. Lash and colleagues [10] report that among breast cancer survivors age 55 and older, 45% had no surveillance mammogram over a four-year period. Similarly, findings based on SEER data revealed that in a cohort of breast cancer survivors age 65 years and older, 38% did not meet ASCO guidelines for mammography over a two-year period [11]. In this cohort, African American survivors were approximately half as likely to have a mammogram compared to White survivors. These findings suggest that the promotion of recommended breast cancer surveillance among African American survivors is an area warranting special attention.

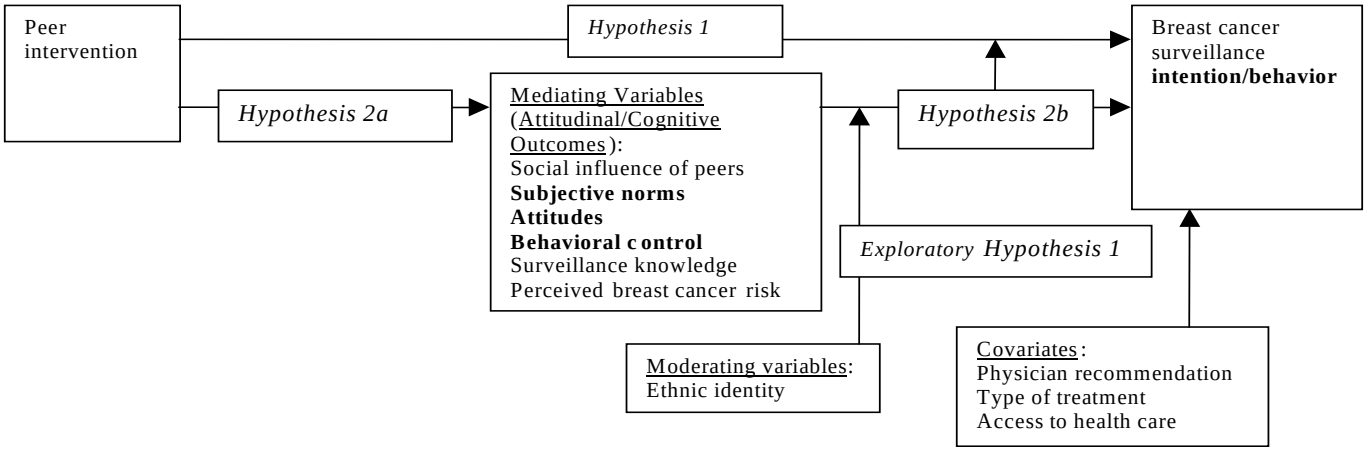
A number of factors may contribute to these surprisingly low mammography rates. Treatment factors may play a role, as survivors who received radiation therapy were significantly more likely to participate in follow-up mammography than women who did not receive radiation therapy [10;11]. Physician factors may also play a role as Lash and colleagues [10] reported that the greatest proportion of mammograms in their cohort were ordered by surgeons as opposed to other specialists, although there were no significant differences. This finding suggests that physician recommendation is likely to be an important factor, as it is with healthy women obtaining screening mammograms. Lack of physician recommendation has been found to be a significant barrier to mammography in African American women (AAW) in particular[12 13] and there are additional barriers observed among healthy AAW that may apply to breast cancer survivors. Failure to adhere to mammography guidelines is significantly associated with limited health care access [14-16 17], low breast cancer knowledge [18-21], and low perceived breast cancer risk [21-23]. Breast cancer surveillance-related fears and worries, such as fear of finding a problem, and concerns about mammography pain, have also been reported by AAW as significant barriers to mammography [21 24 25 26;27]. We are not aware of any data regarding breast self-examination (BSE) adherence among African American breast cancer survivors. However, studies of healthy AAW indicate both underpractice (less than once a month) and overpractice (more than once a month) of BSE [28;29]. BSE may be especially important among breast cancer survivors as several studies indicate that over 70% of breast cancer recurrences are detected by patients themselves as a result of their developing symptoms, such as breast changes, that were identified during the interval between scheduled surveillance appointments or are reported at the time of a scheduled appointment [30-32].

Although there is a considerable body of literature focusing on interventions to increase social support, psychological adjustment, and quality of life among breast cancer survivors, we have found no published data on interventions specially developed to increase post-treatment breast cancer surveillance. One strategy in the development of such an intervention is the adaptation of one developed to increase breast cancer screening among AAW in the general population. Peer interventions by trained lay people who are ethnically, culturally, and socioeconomically similar to the target population are especially compelling. These peer interventions have been increasingly implemented in African American populations and have been shown to increase rates of breast cancer screening [33 34-37]. One successful example of a peer intervention is The Witness Project® [38-40], a breast and cervical cancer education program that integrates the personal insights and experiences of breast cancer survivors with the expertise of lay health advisors (See Resources at MSSM). Several evaluations of this approach have revealed significant increases in screening from pre- to post-intervention ranging from 12% - 33% for mammography and

BSE [38-40]. Although peer interventions are gaining recognition as a viable approach to breast cancer prevention and control [41-43], little research has examined the sources of their success.

Two theories may inform our investigation of the impact of peer interventions. The first, reference group-based social influence theory[44], emphasizes the direct and indirect ways in which groups affect individual behavior. In terms of breast cancer surveillance, peer interventionists are potentially a source of social influence in that they are reference group members and models who: 1) emphasize group values and norms consistent with regular breast cancer surveillance and challenge or reframe group values that are inconsistent, and 2) are "similar others" whose surveillance behavior may be emulated. The influence of norms is also an element of the second theory, the Theory of Planned Behavior (TPB) [45]. TPB posits that one's behavioral intention is predicted by attitudes (one's evaluation of a behavior), subjective norms (one's perception of reference group desires that the individual participate in the behavior) and perceived behavioral control (one's appraisal of his or her ability to engage in the behavior). Studies exploring TPB variables have reported that attitudes, norms, and behavioral control were significant predictors of intention to have a mammogram [46] and intention was the strongest predictor of actual participation [47]. An integration of reference-group based social influence theory and TPB can guide an investigation of the impact of a peer intervention on surveillance (See Figure 1). We speculate that the beneficial effect of a peer intervention is mediated by increases in the following attitudinal variables: 1) survivors' perception of social influence to participate in breast cancer surveillance because the peer interventionists endorse and participate in surveillance themselves; 2) favorable attitudes among survivors because peer interventionists

Figure 1. Integration of reference group-based social influence theory and TPB to investigate breast cancer surveillance (variables originally described by TPB in bold).



address group-specific attitudes; and 3) a sense of behavioral control among survivors because peer interventionists may serve as models whose own surveillance behavior may be emulated. The impact of a peer intervention may also be mediated by increases in cognitive variables such as breast cancer surveillance knowledge, to the extent that peers are viewed as credible sources of information, especially information specific to AAW. It may also be mediated by perceived recurrence risk, as peers may emphasize the vulnerability of AAW as a group. Given our emphasis on social influence theory, it may be important to identify characteristics that vary across individuals and moderate responses to social influence. For example, if a woman has a strong ethnic identity or sense of belonging to African Americans as a group, she may be more likely to respond to social influence than one who does not have strong group ties. This has been demonstrated in previous studies [48 49] in which group norms were more strongly associated with intention and behavior when the individual's identification with the group was strong.

B. HYPOTHESES: The objectives of the research proposed here are: 1) to evaluate the impact of a peer-led survivor surveillance intervention on breast cancer surveillance intention and adherence (mammography, BSE, pelvic exam, physical examination, patient symptom history) among African American breast cancer survivors through a randomized controlled trial; and 2) to investigate the mechanisms (mediational pathways) through which the peer-led intervention impacts surveillance intention and adherence (See Figure 1). **Hypothesis 1**: Participants in the survivor surveillance intervention condition will report greater breast cancer surveillance intention and adherence

following that intervention compared to women in the control group. **Hypothesis 2**: The impact of the intervention on surveillance intention and adherence will be mediated by changes in attitudinal and cognitive variables (breast cancer surveillance-related social influence, attitudes, behavioral control, knowledge and perceived breast cancer risk). **Exploratory Hypothesis 1**: Ethnic identity will moderate the impact of the intervention such that women with stronger ethnic identity will benefit more from the intervention.

Exploratory Hypothesis 2: Ethnic identity and spirituality will moderate the impact of the intervention such that women reporting stronger ethnic identity and spirituality will benefit more from the intervention.

Exploratory Hypothesis 3: Participation in the breast cancer surveillance will be influenced by aspects of the patient/physician relationship including ethnic concordance between patient and physician, patient trust of medical professionals and settings, and quality of communication between patient and physician.

Exploratory Hypothesis 4: Participation in the breast cancer surveillance will be influenced by patient-reported emotional well-being, such as breast cancer-specific distress and concerns about recurrence.

C. OBJECTIVES: Objective 1: To evaluate the impact of a peer-led survivor surveillance intervention on breast cancer surveillance intention and adherence (mammography, BSE, pelvic exam, physical examination) among African American breast cancer survivors through a randomized controlled trial. **Objective 2**: To investigate the mechanisms (mediational pathways) through which the peer-led intervention impacts surveillance intention and adherence (See Figure 1). The proposed study will randomize 409 African American breast cancer survivors to one of two conditions: a survivor surveillance intervention condition or a control condition. All participants will complete a baseline interview assessing sociodemographic and medical information, surveillance intention and adherence, attitudinal and cognitive variables, and ethnic identity. One month following the intervention, all participants will be contacted to complete an interview to assess change in intention, adherence, and attitudinal/cognitive variables. All participants will be contacted again 14 months following the intervention to assess surveillance intention and adherence.

D. METHODS: Participants and sample size: Participants will be AAW recruited from an ongoing Department of Defense-funded parent project ("Genetic Factors in Breast Cancer: Center for Interdisciplinary Research"; PI: Dr. Dana Bovbjerg) at the Mount Sinai School of Medicine in NYC. Participants in the parent project are newly diagnosed African American breast cancer patients identified through hospitals and private specialists in NYC. These women are between 20 and 74 years of age, have a newly diagnosed primary, invasive breast cancer (Stage I, II & III), and no history of previous cancer. Each patient is recruited into the parent project approximately six months after diagnosis. In the proposed study, participants will be AAW who participated in the parent project, age 20-74 years of age and diagnosed with Stage I, II or III breast cancer. Patients will be eligible 3 months post-treatment to ensure time to adjust to survivor status. Primary treatment includes the following: unilateral mastectomy, breast conserving surgery (e.g., lumpectomy, segmental mastectomy, quadrantectomy), adjuvant radiotherapy, and adjuvant chemotherapy. Possible adjuvant hormonal therapy, not included in the definition of primary treatment, will be examined as a possible covariate. Treatment and disease stage information is collected by the parent project. Patients will be excluded if they underwent bilateral mastectomy as part of primary treatment, lack English language fluency, or do not have a working telephone number.

There are 4 methods of recruitment:

1. Participants will be African American women recruited from an ongoing Department of Defense-funded parent project ("Genetic Factors in Breast Cancer: Center for Interdisciplinary Research"; PI: Dr. Dana Bovbjerg) at the Mount Sinai School of Medicine. If participants are identified through this study, a program coordinator from this parent project will review patient records to identify eligible patients who have granted permission to be contacted again regarding other research opportunities. The contact information of these patients will then be given to a research assistant for the current study.

2. Participants will also be African American women who will be identified and referred by their physicians in two methods:

a. Physicians or their representatives will contact potential participants, identified through chart review, via a letter or telephone call in which the purpose of the study will be briefly described. They will then ask if the patient is interested in participating in the study and ask for each patient's permission to be contacted again by a project coordinator via telephone. If a potential participant expresses interest and grants permission to be contacted, the patient's name, address and telephone number will be given to the project coordinator with the proposed study.
b. During a patient visit, eligible patients will receive a study brochure and information about the study. If the patient is interested in the study, her physician will complete a permission-to-contact form and send it to the project coordinator.

3. We will also recruit women through our community partners; organizations and groups that are either staffed by or serve African American breast cancer survivors. During events or meetings at which survivors are present, the leadership will describe the study, distribute the study materials, and obtain a complete permission-to-contact sheet to return to study staff.

4. We will also recruit women in the community through newspaper advertisements. Newspaper advertisements will be placed in community newspapers (e.g., Amsterdam News and AM New York) and flyers will be posted around Mount Sinai School of Medicine and other clinics and community sites that give permission to post.

All eligible women who contact the project coordinator or who are contacted by the coordinator will have study goals and procedures discussed with them. Women who agree to participate will be mailed an informed consent form and HIPAA documents to complete and return via mail. This mailing will also include ASCO surveillance recommendations to ensure that all women are exposed to this information as part of providing at least the standard of care.

According to power analyses (See Statistical Analyses), the proposed study requires a sample size of 300 in order achieve power of over .80 and we expect to recruit and randomize 409 participants over a 26-month period, with at least 300 participants completing the entire study based on attrition rates in previous work. This goal is eminently feasible because the parent project will recruit 800 patients over a four-year period (17 patients/month). Given the timeline of the proposed study, it is not feasible to recruit all eligible patients who participate in the parent project. Starting in Month 6, the parent project will provide the contact information of patients recruited 3-9 months earlier (119 patients) who meet eligibility requirements for the proposed study and gave permission to be contacted about other research. Starting at Month 8 and every two months until Month 30, the parent project will provide the contact information of patients recruited 3-4 months earlier (34 patients/two-month period x 12 two-month periods=408). In total, contact information for 527 patients will be available. Very few of these patients are expected to have undergone bilateral mastectomy as rates of synchronous contralateral breast cancer are low, ranging from 0.3% to 3% across several samples [50-53]. To be conservative, it is estimated that 3% (16 patients) will be ineligible due to bilateral mastectomy. Based on refusal rates reported by other interventions targeting AAW [37-40;54;55] we estimate that of the remaining 511 patients, 20% (102 patients) will refuse to participate in the randomized controlled trial and 409 patients will be randomized. In total, we expect to conduct 14 survivor surveillance intervention presentations over the course of the proposed study. Expected attrition at one-month follow-up is 5% (20 patients) based on data from several longitudinal intervention studies with African American and low-income [37;55] [56]. Expected attrition at 14-month follow-up among the remaining 389 patients is an additional 20% (78 patients) based on similar studies [35;37;55]. Therefore, 311 patients are expected to complete the entire proposed study.

<u>Procedures</u>:

Informed Consent:

Upon first contact, if a woman agrees to participate, a research assistant will read the consent form to her. The consent form will then be sent via mail and the participant will be asked to return it via mail. The PI and research assistants will review consent with particular attention paid to pros and cons of participation. Potential subjects well be asked to verbalized their understanding of the sutdy purpose, procedures, risks and benefits as indication that they understand what involvement of the study requires. Participants will be informed that they will be paid for each interview they complete as part of the study at the time the study is first explained and when they complete informed consent.

If a patient is identified and referred by her physician, the physician or the physician's representative will contact the patient, identified through chart review, during a regular office visit, or via a letter or telephone call in which the purpose of the study will be briefly described. They will then ask if the patient is interested in participating in the study and ask for each patient's permission to be contacted again by a project coordinator via telephone. If a potential participant expresses interest and grants permission to be contacted, the patient's name, address and telephone number will be given to the project coordinator with the proposed study. Patients will then be contacted by telephone by the research assistant who will describe study goals and discuss study procedures. The research assistant will also confirm the treatment the patient received and completion at least three months prior. Women who agree to participate will be mailed an informed consent form and asked to return it via mail. This mailing will also include ASCO surveillance recommendations to ensure that all women are exposed to this information as part of providing at least the standard of care.

Baseline Assessment: The parent project will provide the contact information of recently diagnosed patients who meet eligibility requirements for the proposed study and agree to be contacted about other research. To date, 100% of patients have given permission to be contacted again about other research opportunities. Eligible patients will then be contacted by telephone by a research assistant on the proposed study who will describe study goals and procedures. A strength of recruiting from among the "graduates" of the parent project is that demographic and medical data will be available to evaluate potential participation bias across patients whether or not they agree to participate in the proposed study. Women who agree to participate will be mailed an informed consent form and asked to return it via mail. This mailing will also include informational materials explaining ASCO surveillance guidelines to ensure that all women are exposed to this information. Once the informed consent is obtained, patients will be contacted again via telephone to complete the baseline interview assessing sociodemographic and physician information, surveillance intention and adherence, attitudinal/cognitive variables, and ethnic identity (see Instruments). For assessment of adherence, a guided recall approach will be used that includes the recollection of holidays and local events [57]. Previous projects report a 73-79% rate of agreement between self-report of mammography and medical charts in samples that included a sizable proportion of AAW [57;58] and other studies have shown a 94% rate of agreement [59]. The baseline interview will last at least 45 minutes. Prior to baseline, participants will be randomized to either the intervention condition or control condition (see descriptions below). At the end of the interview, the research assistant, who has been blind to participants' intervention assignment, will open an envelope in which subjects' assignment is indicated. Women who have been randomly assigned to the intervention condition will be offered participation in the intervention within the next 2-3 weeks. Women assigned to the control condition will be informed that they will be contacted again in 5-6 weeks for their second assessment. All women will be informed that they will receive a money order for $20 for their time in completing the baseline assessment.

Intervention Condition: One to three weeks following completion of the baseline, participants in the survivor surveillance intervention condition will attend a presentation that is grounded in the Witness model. During the first five months of proposed study, the Witness model will be tailored for breast cancer survivors and the peer interventionists (breast cancer survivors and lay health advisors) will be specifically trained by the PI. African American interventionists will serve as both "BC survivor witnesses" and lay health advisors. Witness role models (WRMs) share their own experience of cancer diagnosis, treatment, and follow-up care. The program is based, in part, on the African American cultural and spiritual practice of "witnessing" or sharing of personal stories of struggle, faith, and empowerment. WRMs also stress the importance of open dialogue about breast cancer in the

community. Lay health advisors (LHAs) serve a more didactic role and provide education about breast cancer recurrence and recurrence detection.

These African American peer interventionists will be recruited from the pool available in the ongoing Witness Project of Harlem. Peer interventionists will be women who: 1) have strong interpersonal communication skills, 2) ambulatory, with no health concerns which prevent local travel, 3) are accessible by telephone, be at least 21 years old, and 4) are able to read and write. We anticipate that training will include a 4-hour group session followed by a minimum of 2 individual training sessions. Pre-tests and post-tests, as well as practical demonstrations, will be used to evaluate trainees' competence. An incentive of $25 for each interventionists for each intervention conducted. This will be made available to them through money orders presented at the time of the intervention.

Presentations will be conducted at convenient sites at or near the referring hospitals and specialists. Presentations will include: 1) an inspirational introduction, 2) testimony by the breast cancer survivor about her cancer detection, survival and the importance of regular surveillance; 3) review of breast cancer facts specific to AAW by a lay health advisor; 4) discussion of concerns and myths about breast cancer and screening/surveillance that are prevalent among AAW; 5) review of ASCO guidelines; and 6) "hands-on" BSE instruction using the "grid" method, which emphasizes examination of not only the breast but adjacent areas (e.g., chest, armpit). The program is faith-based in that it begins and ends with inspirational content which may include prayer or devotion. This is at the discretion of the interventionists. Additionally, the testimony of the breast cancer survivors may include references to their spiritual faith. The educational program will not be oriented toward a specific religion or set of spiritual beliefs but presenters may refer to their personal spiritual and religious beliefs, which are diverse.

One month following the intervention, participants will be contacted by a research assistant (blind to group assignment) who will conduct a telephone interview to assess surveillance intention and adherence and changes in attitudinal/cognitive variables (see Instruments). The interview will last approximately 30 minutes and women will receive a money order for $20 for their time. Thirteen months following the one-month follow-up assessment, women in the intervention condition will be re-contacted in order to assess surveillance intention and adherence. This assessment will last approximately 10 minutes and all will receive a money order for $20 for their time. Control Condition: After completion of the baseline assessment and a waiting interval matched to the timing of the intervention, women in the control condition will undergo identical assessments procedures as described above.

Instruments: The majority of the following survey instruments are standardized measures and have documented reliability and validity: Sociodemographic and Physician Information; Breast Cancer Surveillance Intention and Adherence/Physician Recommendation; Perceived Access to Health Services [14]; Perceived Social Influence to Participate in Breast Cancer Surveillance; Breast Cancer Surveillance Attitudes [21;60;61]; Behavioral Control [62]; Breast Cancer Surveillance Knowledge; Perceived Breast Cancer/Recurrence Risk [63]; Ethnic Identity [64;65].

Table 1 below presents the points of administration for all measures. Unstandardized measures will be pilot tested during the first 5 months of the proposed study.

Table 1.

Parent Project	**Time 1: Pre-intervention/Baseline**	**Time 2: Post-intervention (1 month)**	**Time 3: Post-intervention (14 months)**
	Sociodemographic and physician information		
Stage of Diagnosis/Type of	Breast cancer screening surveillance	Breast cancer screening surveillance	Breast cancer screening

Treatment/Time of Treatment	intention/adherence & physician recommendation	intention/adherence & physician recommendation	surveillance intention/adherence & physician recommendation
	Surveillance-related attitudes	Surveillance-related attitudes	
	Perceived social influence to participate in surveillance/norms	Perceived social influence to participate in surveillance/norms	
	Behavioral control	Behavioral control	
	Breast cancer surveillance knowledge	Breast cancer surveillance knowledge	Breast cancer surveillance knowledge
	Perceived breast cancer/recurrence risk	Perceived breast cancer/recurrence risk	Perceived breast cancer/recurrence risk
	Ethnic identity/racial pride		
	Impact of events		Impact of events scale
	Perceived access to health care		
	Exposure/interest in genetic testing	Exposure/interest in genetic testing	Exposure to mammography related information

Potential Covariates:

Sociodemographic and Physician Information: A basic sociodemographic questionnaire will be used to assess age, marital status, parental status, education, income, health insurance status and ethnicity. This measure also asks about what type of physician the participant sees for follow-up care since completion of primary breast cancer treatment. This measure will be included at baseline assessment.

Physician Recommendation: Items assessing physician recommendation for at surveillance are included in the measure of surveillance intention and adherence administered at all three assessments.

Perceived Access to Health Services (PAHS) [14] is a 10-item scale with items that address cost, convenience and the existence of a health care provider relationship. The PAHS was administered to a sample of 352 African American women and results showed adequate internal consistency ($\alpha = .78$). In the proposed research, the PAHS will be administered at field survey/baseline assessment and at the post-intervention assessment

Outcome Measures:

Breast Cancer Surveillance Intention and Adherence: This measure, which was developed by the PI and colleagues, will be used to assess actual practice of mammography, physical examination/patient history, BSE and pelvic exam. The measure also assesses intention through an item developed by Sheeran and Orbell [62]. This measure also includes items regarding physician recommendation of each screening modality. This measure will be included at all three assessments.

Mediators:

Perceived Social Influence/Group Norms to Participate in Breast Cancer Surveillance: Thirteen items were developed by the PI and colleagues, will be used to participants' perceptions of social influence from other African American women to participate in regular breast cancer surveillance, as well as perception of reference group norms regarding surveillance. This measure also includes items that assess the social influence of significant others, such as family, friends, etc. The response key is a Likert-type scale ranging from 1 (strongly disagree) to 5 (strongly agree). This measure will be administered at baseline and one-month post-intervention.

Breast Cancer Surveillance Attitudes: A 34-item questionnaire will be used to assess participants' attitudes about mammography and breast cancer surveillance in general. This measure was based on previous work focusing on the pros and cons of cancer screening [60;61], as well as mammogram concerns [21]and breast cancer stigma [68] . The response key is a Likert-type scale ranging from 1 (strongly disagree) to 5 (strongly agree). In previous work, similar measures demonstrated strong internal consistency, with Cronbach's alphas ranging from .74 - .83. This measure will be administered at baseline and one-month post-intervention follow-up.

Behavioral Control Regarding Breast Cancer Surveillance: Twelve items will be used to assess participants' sense of how easy it will be to engage in surveillance behaviors (mammography, physical exam/patient history, BSE, and pelvic exam) and how confident they are that they will do so. These items were adapted from Sheeran and Orbell [62], who report moderate internal consistency (α=.67). This measure will be administered at baseline and one-month post-intervention follow-up.

Breast Cancer Surveillance Knowledge will be assessed through a 9-item face-valid measure which assesses participants' understanding of breast cancer, issues that are relevant to breast cancer survivors, and breast cancer surveillance guidelines. Response format is "yes," "no," or "not sure."This questionnaire will be administered at baseline and at the one-month post-intervention assessment.

Perceived Breast Cancer/Recurrence Risk will be assessed through rating scales ranging from 0 to 100 that ask participants to indicate how likely it is that they will develop breast cancer again, as well as how serious they think it would be if they developed breast cancer again. This scale is adapted from Weinstein [63] who observed likelihood by severity interactions for health-protective behaviors. This measure will be administered at baseline and one-month post-intervention follow-up.

Moderators:

Ethnic Identity will be assessed by two measures. The first is a 7-item measure of racial pride and connection to other African Americans that has demonstrated strong internal consistency in African American female samples (α=.67) [64]. The second is a measure of Africentrism, developed to assess the degree to which a person adheres to values of racial unity, self-determination, and collectivism [65]. Based on administration in African American samples, Cronbach's alphas for this scale range from .74 - .82. The response key is a Likert-type scale ranging from 1 (strongly disagree) to 4(strongly agree).

In order to address exploratory hypotheses, the following measures will be added. In order to address participant burden, most of these measures will be not be a part of the research interview but participants will have the option of completing them on their own and returning via U.S. mail.

Spirituality will be assessed by an integration of items from two measures that have demonstrated strong reliability in African American female samples. The first is a measure of religiosity (α = .88) and the second is a measure of spiritual locus of control (internal vs. external) (α = .73). Three additional items will be included to assess religious behaviors

(Participants will have the option of completing these measures independently (rather than via interview) and returning them via U.S. mail.)

The Impact of Event Scale (IES) is commonly used to measure cancer-specific distress. These 16 items assess intrusive and avoidant stress reactions to a specific stressor, in this case, the threat of prostate cancer. Participants will be asked to rate how frequently each thought or behavior occurred during the past week. These items have demonstrated strong internal reliability in previous work (alpha=.86)

Genetic Testing Awareness and Interest will be assessed through the following five items: How much have you heard or read about genetic testing for breast cancer risk?; At the present time, how interested are you in getting genetic testing for breast cancer risk?; Now that such a test is currently available, which of the following best describes your intentions? ; Do you have any relative who has been diagnosed with breast or ovarian cancer?; Is one of these relatives diagnosed with breast or ovarian cancer your parent, your sibling or your child? *(Participants will have the option of completing these measures independently (rather than via interview) and returning them via U.S. mail.)*

The Concerns About Recurrence Scale is a 30 item structured assessment of the nature of women's fears about breast cancer recurrence. This measure has demonstrated high reliability in previous samples (alpha=.87). *(Participants will have the option of completing these measures independently (rather than via interview) and returning them via U.S. mail.)*

Medical Mistrust: Two measures will be administered to assess different aspects of medical trust and mistrust. The Group-Based Medical Mistrust Scale (GBMMS) will be used to assess suspicion of mainstream health care systems and health care professionals and the treatment provided to individuals of the respondent's ethnic or racial group. The GBMMS is a 12-item scale has demonstrated strong reliability in AA and Latino samples ($\alpha = .83$). The Medical Mistrust Index (MMI) is an 11-item scale that will be administered to assess one's generalized trust in medical care. The MMI includes three subscales: competence, or the expectation that healthcare providers are adequately trained and technically proficient; control, the belief that those entrusted with one's care will not inappropriately defer to the judgement of others; and agency, or the belief that competing interests will not supercede the best interest of the patient. *(Participants will have the option of completing these measures independently (rather than via interview) and returning them via U.S. mail.)*

Participatory Decision Making will be assessed by the Control Preferences Scale (CPS). The CPS includes two sets of five statements describing possible roles in medical decision-making (active, collaborative or passive). Participants will be asked to first describe their preferred role in their medical and then asked to describe the role they believe they have in their medical care. *(Participants will have the option of completing these measures independently (rather than via interview) and returning them via U.S. mail.)*

Intervention Evaluation: A brief 14-item measure will be administered immediately after the intervention in order to assess participants evaluation of the actual intervention and the presentation of educational material.

Statistical Analyses

Preliminary Analytic Considerations: **Data Characteristics**: We will examine the distribution of each measure used in the study and make decisions regarding possible transformations required to meet the assumptions of the statistical tests that will be employed. **Identification of Covariates**: While the research design involves random assignment to intervention condition, it is still possible that screening behavior may be related to sociodemographic (e.g. age, education) and/or medical variables (e.g., type of primary treatment, physician recommendations regarding screening, health care access, etc.) whose inclusion would increase the power of the analyses. Potential covariates (using somewhat liberal p-values: $p \leq 0.15$) will be examined to determine whether they should be included in the analyses described below.

Hypothesis 1: Participants in the survivor surveillance intervention condition will report greater breast cancer surveillance intention and adherence following that intervention compared to women in the control group. **Statistical Analysis**: The first outcome measure is surveillance intention. Since intention to adhere to different screening

measures may be affected by different covariates, we plan to examine each screening intention individually. A mixed linear models repeated measures design will be used (SAS PROC MIXED). In these analyses, baseline intention for each screening activity will be treated as a covariate and the grouping variable as a main effect along with other covariates identified in earlier analyses. Since adherence is a binary outcome and adherence to different screening behaviors may also involve different covariates, each screening behavior will be examined individually using a Generalized Estimating Equations (GEE) approach implemented through the SAS procedure, GENMOD. Baseline intention will be treated as one covariate and intervention group will be the main focus with adherence intention immediately after the intervention and twelve months later as the outcomes. **Power Analysis**: A case-control design by Erwin and colleagues [40] has documented significant effects ($p<.0005$) of the Witness Project on BSE and mammography among healthy AAW (See Background). For purposes of power in this study, we will assume similar changes in our intervention and control groups. The effect sizes for differences in proportions are in the moderate range. With an N = 300, alpha = 0.01, power is expected to be 90% - 95%.

Hypothesis 2: The impact of the intervention on surveillance intention and adherence will be mediated by changes in attitudinal and cognitive variables (breast cancer surveillance-related social influence, attitudes, behavioral control, knowledge and perceived breast cancer risk). **Statistical Analysis**: This hypothesis is concerned with mediating mechanisms and will be tested following Baron and Kenny's recommendations [66]. Since there are repeated measures, each step will involve a mixed linear model (SAS PROC MIXED) with appropriate covariates. The following hypotheses will be evaluated: 1) intention and adherence following the intervention and 14 months later will be compared to the control group with baseline data as covariates; 2) participants will have greater changes in attitudinal/cognitive variables following the intervention and 14 months later compared to the control group with baseline attitudes and cognitions as covariates; and 3) attitudinal/cognitive variables will be related to intention and adherence immediately after the intervention and 14 months later with appropriate baseline information included as covariates. Assuming the Baron and Kenny criteria [66] have been met, the mediating variable (attitudinal/cognitive variables) will be entered into the equation predicting each outcome (intention and adherence immediately after the intervention and 14 months later). If mediation occurs, the parameter estimate for group will no longer be significant. We shall test the significance of the mediating effect using a procedure described by Baron and Kenny [66]. **Power Analysis**: Since this hypothesis is concerned with mediating processes, a discussion of power is not relevant.

Exploratory Hypothesis 1: Ethnic identity will moderate the impact of the intervention such that women with stronger ethnic identity will benefit most from the intervention. We anticipate that the individual difference variables act as moderators of the effectiveness of the intervention such that breast cancer surveillance intention and adherence will vary at different levels (e.g., weak ethnic identity vs. low ethnic identity). **Statistical Analysis**: If such moderator effects are present, they should operate as interactions between the pre- and post-intervention time period. Because the possible interactive effects of each of these individual difference variables may be obscured if all interaction terms are included in a single model, we will first examine the effects of each of these individual difference variables on breast cancer screening outcomes graphically, grouping first by baseline, immediately after the intervention, and at the 14 month follow-up. This preliminary examination may provide guides as to which of the two individual difference variables is the most likely candidate for interaction effects. Based on the graphical results, we shall enter the interaction terms sequentially using the approach described in Primary Hypothesis 1.

Risks/Benefits Assessment

Potential risks of participation in psychosocial research include emotional discomfort or distress that might result from being asked about personal cancer risk or recurrence risk during assessments. The interviewers will be trained to remind participants of the voluntary nature of the research and that participants have the right to refuse to answer specific questions and may stop at any time for any reason. The interviewers will also be able to contact the clinical psychologists associated with the project and be able to provide referrals if necessary. The alternative procedure would be non-participation in the research component. Potential benefits include learning more about breast cancer surveillance recommendations for breast cancer survivors. It is believed that the benefits outweigh the risks.

Disposition of Data

The proposed study will provide for the same level of confidentiality as is standard with medical information. All participants will be assigned a numeric code so they cannot be identified in study data analyses, publications, and presentations. Research records will be kept in locked and secured files. Only the PI and individuals who are assisting with this project will have access to these records. A cross-referenced file that will link numeric codes with participants' consent forms will be secured by the PI. Data will be entered into a computer database that is saved on a computer disk rather than a computer hard drive. This disk will be secured by the PI.

Adverse Events

In the proposed study, an adverse event will be defined as the occurrence of significant emotional distress that results from being asked about personal cancer risk or recurrence risk during assessments. If such an adverse event should occur, the interviewer conducting the assessment will contact the PI, who is a licensed clinical psychologist who will conduct a brief psychological assessment and refer the participant to appropriate psychological care. Adverse experiences that are both serious and unexpected will be immediately reported by telephone to the USAMRMC, Deputy of Regulatory Compliance and Quality and by facsimile. A written report will follow the initial telephone call within 3 working days. The same procedure will be followed in reporting the adverse event to the Institutional Review Board of Mount Sinai School of Medicine where the research is being conducted.

Modification or Amendments to Protocol

Any and all modifications or amendments to the protocol will be submitted to the Institutional Review Board of Mount Sinai School of Medicine for review and approval, and the HSRRB for second level review and approval. The same procedure will be followed if the study is terminated before completion.

DEPARTURE FROM PROTOCOL

Any departure from the protocol will noted in participant records and notification will be sent to the Institutional Review Board of Mount Sinai School of Medicine, as well as the HSRRB.

Principal Investigator:

Hayley Thompson, Ph.D. is an instructor at the Derald Ruttenberg Cancer Center at Mount Sinai School of Medicine. Dr. Thompson will be responsible for all aspects of the research protocol. Dr. Thompson has extensive experience working with African Americans in the development and coordination of culturally relevant programming, the exploration of sociocultural factors and health outcomes, and conducting health-related psychosocial assessments. She also has experience in research project management. In addition, she is Training Coordinator for The Witness Project® of Harlem (WPH). This experience will enable her to develop training tools for women who will be implementing the survivor surveillance intervention described in the proposed study. Dr. Thompson will also conduct the actual training sessions. She will also directly supervise intervention delivery and attend all intervention presentations. Dr. Thompson will supervise the research assistant in subject recruitment, administration of questionnaires, and other support tasks. She will also supervise the data entry clerk. Dr. Thompson will also establish quality control checks and design monthly reports on recruitment and follow-up. Dr. Thompson will work closely with Drs. Valdimarsdottir, Winkel and Bovbjerg and Ms. Jandorf on data analysis and preparation of results for presentations and publications. Her time commitment will be 30% on all years of the study.

Co-Investigators:

Heiddis Valdimarsdottir, Ph.D. will serve as a co-investigator. Dr. Valdimarsdottir is an assistant professor at the Derald Ruttenberg Cancer Center at Mount Sinai School of Medicine and has worked closely with Dr. Thompson on the development of culturally-tailored interventions targeting African American women at increased genetic risk for breast cancer. Dr. Valdimarsdottir is currently the Principal Investigator of the Department of Defense-funded project, "Impact of Culturally Tailored Counseling on Psychobehavioral Outcomes and BRCA Decision Making Among Women with Breast Cancer" and has extensive experience in the psychological evaluation of individuals at familial risk for breast cancer. In terms of the proposed study, Dr. Valdimarsdottir will work with Dr. Thompson to develop the content of the survivor surveillance intervention, as well as to pilot test and refine measures. Dr. Valdimarsdottir's time involvement will be 10%.

Lina Jandorf, M.A. will serve as a co-investigator. Ms. Jandorf is a research assistant professor and Outreach Director at the Derald Ruttenberg Cancer Center. Ms. Jandorf is Project Coordinator of the Witness Project of Harlem and is also responsible for all aspects of outreach, recruitment and interviewing as the head of recruitment core of the Department of Defense-funded project, "Genetic Factors in Breast Cancer: Center for Interdisciplinary Research," which will recruit 800 African American breast cancer patients over a four-year period. She will assist Dr. Thompson in maximizing participant recruitment and will work with Dr. Thompson to develop training tools to develop training tools to educate peer interventionists. Her time commitment will be 5% during all years of the study.

Dana Bovbjerg, Ph.D. will serve as a co-investigator. Dr. Bovbjerg is the head of Biobehavioral Medicine Program at the Derald Ruttenberg Cancer Center at the Mount Sinai School of Medicine. He is also principal investigator for the Department of Defense-funded project, "Genetic Factors in Breast Cancer: Center for Interdisciplinary Research," the parent program from which participants will be recruited for the proposed study. Dr. Bovbjerg has expertise in the investigation of biobehavioral consequences of stress in several populations, including healthy volunteers, individuals at high risk for cancer, and cancer patients. Dr. Bovbjerg will work closely with Dr. Thompson in the implementation of the proposed study and collaborate directly with Dr. Thompson on all aspects of the research design as well as contribute to data analysis and the preparation of manuscripts. His time commitment will be 2.5 % during all years of the study.

Other Personnel:

Research Assistant TBN (100%): A research assistant will be hired to recruit participants, conduct baseline and follow-up interviews, manage a tracking system for the multiple assessments, perform basic data management and oversee the mailing of participant incentives. This full-time research assistant will also be responsible for the scheduling and coordination of survivor surveillance intervention presentations and will assist with peer interventionist training. This research assistant will attend intervention presentations along with Dr. Thompson to record the attendance of study participants and maintain the integrity of the randomized controlled trial. This program coordinator will have 100% involvement for all years of the study.

Data Entry Clerk TBN: An assistant will be hired to enter baseline and post-intervention data as well as basic data management. The time commitment for the data entry clerk will be 25% for the first 3 years of study.

Consultants:

Deborah Erwin, Ph.D. is an associate professor at the University of Arkansas Medical School, Division of Surgical Oncology. She is the co-founder of the Witness Project and is the Principal Investigator the project entitled A Replication and Dissemination of the Witness Project@ funded by the Centers for Disease Control. Dr. Erwin will work with Dr. Thompson to develop training tools to educate peer interventionists. Dr. Erwin will also work with Dr. Thompson to refine measures and assessment strategies. Dr. Erwin will be paid at a rate of $700 per day (7 days in Year 1 = $4900) in addition to the costs of her transportation to and accommodations and amenities in New York City ($1600).

Gary Winkel, Ph.D. is a professor at the City University of New York. He has provided statistical expertise and consultation with psychosocial investigators at the Derald Ruttenberg Cancer Center for six years. Dr. Winkel's statistical expertise is in regression strategies as well as methods of analyzing longitudinal data with missing data. He teaches several graduate level statistics courses, including structural equation modeling and regression. He will work closely with Dr. Thompson in all aspects of the data interpretation. He is extremely well-qualified and familiar with the study design and methods to be used in the proposed research. Dr. Winkel will be paid at a rate of $100 per hour (30 hours in Year 3; 30 hours in Year 4).

Permission to Contact
Physician referral

Increasing Breast Cancer Surveillance Among
African-American Breast Cancer Survivors

Some of your breast cancer patients may be eligible to participate in the research study titled, "Increasing Breast Cancer Surveillance Among African-American Breast Cancer Survivors."

This study will enroll African American/Black breast cancer patients who:

- **Are between ages 20-74;**
- **Are between 3 months and 48 months post-primary breast cancer treatment (Primary breast cancer treatment includes surgery, radiation therapy, and chemotherapy. Hormonal therapy is not a part of primary treatment for the purposes of this study and patients currently undergoing hormonal therapy are eligible);**
- **Have only one breast cancer diagnosis;**
- **Have not been diagnosed with any other type of cancer before or after that breast cancer diagnosis;**

The study involves 3 telephone interviews over the course of one year and an invitation to an educational program developed especially for Black breast cancer survivors.

Patients will receive compensation for their participation in the study.

If you have a patient who might be interested and you would like a study coordinator to contact them about the study, please complete the information below and FAX it to Michelle Foster at (212) 849-2564.

Patient Name:
_____

Date of Discussion: _____

Patient Address: _____
_____

Patient's Telephone #: _____

Physician Signature:
_____

I have talked to this patient and she has given permission to be contacted regarding this research study.

Permission to Contact

Community Leadership

Increasing Breast Cancer Surveillance Among
African-American Breast Cancer Survivors

Some of your breast cancer patients may be eligible to participate in the research study titled, "Increasing Breast Cancer Surveillance Among African-American Breast Cancer Survivors."

This study will enroll African American/Black breast cancer patients who:

- **Are between ages 20-74;**
- **Are between 3 months and 48 months post-primary breast cancer treatment (Primary breast cancer treatment includes surgery, radiation therapy, and chemotherapy. Hormonal therapy is not a part of primary treatment for the purposes of this study and patients currently undergoing hormonal therapy are eligible);**
- **Have only one breast cancer diagnosis;**
- **Have not been diagnosed with any other type of cancer before or after that breast cancer diagnosis;**

The study involves 3 telephone interviews over the course of one year and an invitation to an educational program developed especially for Black breast cancer survivors.

Patients will receive compensation for their participation in the study.

If you are interested and you would like a study coordinator to contact them about the study, please complete the information below and FAX it to Michelle Foster at (212) 849-2564.

Name:

Date of Discussion: _____

Address: _____

_____

Telephone #: _____

Best Time to Call: _____

Signature: _____

MSSM GCO # 02-0561 (01)
Approved through 6/8/2007

DRAFT OF NEWSPAPER ADVERTISMENT AND FLYER

AFRICAN AMERICAN/ BLACK WOMEN NEEDED FOR RESEARCH STUDY

The Department of Oncological Sciences at Mount Sinai School of Medicine will be holding several faith-based educational programs focusing on African American/Black breast cancer survivors and their follow-up care.

You are eligible for a research study about these programs if:

- **A woman between the ages of 20-74**
- **Are between 3 months and 48 months post-primary breast cancer treatment (Primary breast cancer treatment includes surgery, radiation therapy, and chemotherapy. Hormonal therapy is not a part of primary treatment for the purpose of this study.**
- **Have only one breast cancer diagnosis**
- **Have not been diagnosed with any other type of cancer before or after that breast cancer diagnosis**

The study involves 3 telephone interviews over the course of one year and an invitation to an educational program developed especially for Black breast cancer survivors. You will be compensated for your time.

If interested please contact Michelle Foster by email at Michelle.Foster@mssm.edu or phone at 212-659-5477.

GCO # 02-0561 (01)
MSSM IRB approved through 6/8/2007

Survivors in spirit

Looking ahead to life after breast cancer treatment

Survivors in Spirit is part of a research study through Mount Sinai School of Medicine

You will be compensated for your participation in this study.

If you are interested in participating please contact study coordinator, Michelle Foster at 1-212-659-5477

Principal Investigator:
Hayley Thompson, Ph.D
Department of Oncological Sciences
Mount Sinai School of Medicine
1-212-659-5648

GCO # 02-0561 (01)
MSSM IRB approved through 6/8/2007

Survivors in Spirit **is a faith-based educational program focusing on black breast cancer survivors.**

During the program, you will hear from other Black breast cancer survivors who share their personal testimonies of cancer diagnosis, treatment, and follow-up care.

You will also hear information about breast cancer recurrence and recommendations for follow-up care after breast cancer treatment.

Study participants will attend the program and have three telephone interviews over the course of a year.